REMARKS/ARGUMENTS

Claims 1, 4-9 and 11-16 and 63-70 are active. Non-elected claims have been cancelled without prejudice to their presentation in a divisional application. The limitations of claim 10 now appear in claim 1. The claims have been revised for clarity and to remove multiple dependencies. New claims 63-66 find support in original claim 1 and on pages 21-24. SEQ ID NO: 12 is described in the original sequence listing and at the bottom of page 21. HLA-A2 and HLA-A24 associations are described at the top of page 24. Claims 69 and 70 track limitations in original claims 4 and 8. No new matter is believed to have been added. Favorable consideration of these amendments and allowance of this application are respectfully requested.

Restriction/Election

The Applicants previously elected with traverse **Group I**, claims 1-16, directed to a method of selecting a patient and SEQ ID NO: 2. The requirement has been made FINAL. The Applicants respectfully request that the claims directed to any non-elected subject matter or any other subject matter that is withdrawn from consideration which depend from or otherwise include all the limitations of an allowed elected claim, be rejoined upon an indication of allowability for the elected claim, see MPEP 821.04. Applicants understand that Examination will be extended to additional species upon an indication of allowability for the elected species.

Rejection—35 U.S.C. §112, first paragraph

Claims 1-6, 8-14 and 16 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description. Examination has been limited to the elected species of SEQ ID NO: 2. The amino acid sequence of SEQ ID NO: 2 is completely disclosed.

Therefore, this rejection would not apply to the claims as now under examination. Moreover, claim 1 as amended does not recite any mutant or variant peptides and "[t]hough understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). Consequently, this rejection cannot be sustained.

Rejection—35 U.S.C. §103(a)

Claims 1-12 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over McNeill, et al., WO 02/28414, in view of Altman, et al., Science 274: 94. MacNeill does not disclose or suggest selecting or qualifying patients for subsequent vaccine treatment using the frequency of CTL precursor cells as an indicator. To the contrary, the prior art thought it was quite difficult to select patients based on the frequency of CTL-precursor cells as indicated on page 2, last paragraph of the specification:

> Frequency of CTL precursor cells were measured using HLA tetramer and peripheral blood mononuclear cells (PBMC) of melanoma patients and reported in several papers; however, **they show that the frequency of CTL precursor cells specific for tumor antigen peptide is low** (J. Immunother. 24: 66, 2001、Hum. Gene. Ther. 13: 569, 2002). From these results, **it has been regarded that the frequency of existence of CTL precursor cells specific for antigen is generally low and that it is difficult to select patients suitable for a cancer vaccine on the basis of the frequency of CTL precursor cells as an indicator**.
> (emphasis added).

In distinction to the prior art, the inventor discovered that WT1 specific CTL precursor cells, especially of the effector type, are found in significantly higher frequencies or amounts in cancer patients than the CTL precursor cells specific to other tumor antigens. The prior did not suggest or provide a reasonable expectation of success for the invention

because it did not recognize the high frequency of ST1 specific CTL precursor cells was useful in selecting a patient who would be responsive to WT1 vaccine. Accordingly, this rejection cannot be sustained.

Rejection—35 U.S.C. §103(a)

Claims 13-15 were rejected under 35 U.S.C. §103(a) as being unpatentable over McNeill, et al., WO 02/28414, in view of Altman, et al., Science 274: 94, and further in view of Nagai, et al., J. Infect. Dis. 183:197. This rejection cannot be sustained for the reasons given above. Nagai, page 19, 2nd col., last paragraph, was relied upon for teaching that effector cells are $CD8^+/CD45RA^+/CD27^-$. However, it does not supplement the lack of suggestion in the primary references or provide any reasonable expectation of success for the claimed method. Therefore, this rejection cannot be sustained.

Conclusion

This application presents allowable subject matter and the Examiner is respectfully requested to pass it to issue. The Examiner is kindly invited to contact the undersigned should a further discussion of the issues or claims be helpful.

Respectfully submitted,

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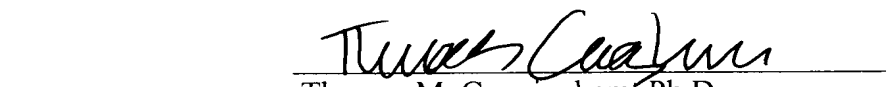

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